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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287

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EXAMINER	
JIANG; DONG	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/089,009	**Applicant(s)** GOLDMAN ET AL.	
	Examiner Dong Jiang	**Art Unit** 1646	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3,5,9,11-15 and 22-29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: No amendment accompanied the response.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1, 3, 5, 9, 11-15 and 22-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the last Office Action mailed on 6/16/06, and for the reasons below.

Applicants argue that, as indicated in the specification, the 5F7 antibody co-immunoprecipitated IL-2R (page 37, lines 28-31), which strongly suggests that the ILRAPs were associated with the IL-2R, and that the specification clearly establishes that the claimed polypeptides associate with IL-2R (also see Examples 5 and 6). Applicant argument has been fully considered, but it is not persuasive because the rejection is completely based on applicants disclosure (lack of evidence indicating the association), and evidence (indicating lack of association: item 8 and Exhibit 3, lane 8) provided in the declaration filed on 3/21/06. For example, on page 37 of the specification, it is merely said that close inspection reveals a third faint band at approximately 55 kDa, the MW of IL-2R. However, such a band is present across the "board" in the result of Exhibit 3, in all lanes (including "unrelated" lanes 5 and 7), even in the lanes pre-cleared with anti-Tac (anti-IL-2Ra), which supposedly show the lack of said IL-2R. Additionally, it is not explainable that 5F7 antibody is able to co-precipitate the IL-2R (the 55 kD band), but the reverse is not true, i.e., anti-Tac is not able to co-precipitate the ILRAPs, assuming they were associated, as asserted. It is clear that the "55 kD band" is non-specific. Further, there is no direct evidence in the specification showing the direct association between the claimed ILRAPs and the IL-2R. Therefore, in the absence of such evidence, and the presence of the opposing evidence provided by applicants, the instant rejection is maintained.

Furthermore, claims 1, 3, 5, 9, 13-15, 22-25 remain rejected, and the new claims 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the reasons of record set forth in the previous Office Actions mailed on 6/304, 4/19/05, 10/18/05, and 6/16/06, and for the reasons below.

The declaration by Dr. Bamford filed under 37 CFR 1.132 has been considered but is ineffective to overcome the prior art references by Colamonici et al. because the declaration is largely opinion only, and presents no further supporting data/evidence, such as results from experiments using Hut 102 cells, from which the claimed polypeptides are derived, and based on which the instant rejection is made as the same cells were also used by Colamonici (note, although such is not required by law, it would be helpful as more direct evidence).

Applicants opinion and argument have been fully considered, but they are not persuasive. In the declaration, it is stated that "I do not believe that it is reasonable to assume that the 37 kD protein and a protein determined to be 32-34 kD via SDS-PAGE are the same protein, ... and that the 20 kD protein is equivalent to a protein determined to be 26-28 kD" (item 2); "I would not expect that proteins having a 10% difference in MW as determined by SDS-PAGE to be the same protein" (item 3); "in my opinion, ... the 37 kD protein identified in Hut 102 cells is the same 37 kD protein identified in MLA-144 given the experimental conditions" (item 5); "Exhibit 4 demonstrates that IL-2R associated proteins found on MLA-144 cells, including the 37 kD protein described in the Colamonici's reference, do not form a complex with the 5F7 antibody", and "based on these results, I would not expect the 37 kD protein of Hut 102 cells identified in Colamonici's reference to form a complex with the 5F7 antibody" (item 6). These arguments are not persuasive because, with respect to the different cell lines used, as addressed in the last Office Action, they represent different cell sources from that used by applicants for the identification of the claimed polypeptides. Therefore, such is not proper comparison. One's opinion or belief would not be sufficient to prove that two molecules with close MW (based on SDS-PAGE), yet identified from different cell sources would be the same or different in the absence of any direct evidentiary support.

With respect to the difference in MW, as addressed previously, variation in MW determined by SDS-PAGE can happen between different experiments as the migration of molecules is influenced by experimental conditions, which involve multiple factors such as the concentration of the gel, buffer (ionic strength), pH, temperature, time of running. For example, Colamonici calls the new putative g-subunit of the IL-1R "p95-110 subunit" (the abstract), indicating the nature of relative MW estimation of SDS-PAGE, and the possible deviation in MW determination by SDS-PAGE, which, in this case, is 15 kD (>10%). Further, more importantly, in the instant case, the results being compared are not even from the two repeated experiments following the same conditions, i.e., it is applicants SDS-PAGE vs. Colamonici's SDS-PAGE, which can not be properly compared without knowing the experimental conditions used in each case, and the deviation of such a comparison could be even more significant than that obtained interexperimentally. Furthermore, the fact that there may exist a 10% MW difference does not make the claims any less anticipatory because there is no evidence to suggest that a complex would not form between the antibody 5F7 and the antigen in the prior art.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER